REMARKS

Reconsideration of this application is respectfully requested in view of the above amendments and following remarks. This response is also accompanied by an Information Disclosure Statement and appropriate fee.

The specification has been amended to correct an obvious typographical error in the chemical name of compound (1) at page 25, i.e., the "11" at the start of the name has been changed to "1." The correct name appears in Example 39 of the application, as well as in several other places such as at p.18, line 9; p. 20, line 8, and in claim 15, compound (29).

In the current listing of claims, the pending claims are : 2-15, 17-19, 25 and 30. In the pending claims, Claims 2, 3, 13, 14, 17, 19 and 25 are currently amended, and claim 30 is newly added. Claims 1 and 21 are cancelled by this amendment.

The following relates to the cancellation of claim 1. U.S. 2003/0086923 ('923) published on May 8, 2003, and is a continuation of U.S.S.N. 09/716,554 filed on November 20, 2000. The '923 publication is listed on the accompanying IDS along with other publications. At page 3 of '923, just above paragraph [0025], appears a drawing of a chemical structure denoted as "Compound 4." Compound 4 falls within the generic scope of claim 1 and therefore has been cancelled.

It is pointed out that Compound 4 in '923 does not fall within the scope of instant claim 2; please see the proviso in claim 2 which appears in part (b) of the definition of "Y", and reads as follows:

> "provided that when R^1 is $-CF_3$, R^2 is n-propyl, and Z is n-proplyoxy, the 6-membered heterocyclic ring is not unsubstituted 5,6 dihydrouracil".

The pending claims are believed to be patentable over the '923 publication as well as the additional publications noted on the IDS.

Claim 2 has been amended to correct an obvious typographical error, i.e., "R_1" and "R_2" were corrected to read "R^1" and R^2", respectively, in the proviso recited just above.

Claims 3, 13, 14, 17, 19 and 25 have all been amended to change their dependency from claim 1 to claim 2.

New claim 30 depends upon claim 2. All the compounds recited in claim 30 are recited and supported in the specification at page 25, line 17, through page 26, line 29. Claim 30 recites the corrected name for compound (1), as discussed above for the amendment to the specification.

Cancelled claim 21 will be discussed below.

No new matter has been added to this application by the amendments noted above.

Claim Rejections Under 35 USC § 112

Claims 1-15, 17-19, 21 and 25 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated:

> i) In claims 1, 2 and 15, the phrase "and pharmaceutically acceptable salts, esters and tautomers thereof" is inappropriate Markush language. The phrase should be rewritten as for example, "or a pharmaceutically acceptable salt thereof."
> ii) The kinds of "esters" of the compound of formula I are unclear. Where are these esters formed and what do they look like?

Applicants respectfully traverse this rejection. It is pointed out that rejections of claims 1 and 21 are rendered moot by their cancellation.

With respect to point (i), the MPEP states:

> "2173.05(h) Alternative Limitations
> I. MARKUSH GROUPS
> Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C."

While Markush groups are one acceptable form of alternative expression, they are not the only form that satisfies 35 USC § 112, second paragraph. Applicants have not used a Markush format, but have clearly expressed that pharmaceutically acceptable salts, esters and tautomers of compounds falling within the generic scope of claim 2, and of the species recited in claim 15, are included within the scope of these claims. The Examiner has not explained, nor do Applicants see, how the existing language presents uncertainty or ambiguity with respect to the scope or clarity of the claims. The language currently used in claims 2 and 15 provides at least the same degree of clarity as the alternative language suggested by the Examiner.

With respect to point (ii), esters of compounds within the scope of Formula I are possible whenever a free carboxylic acid group is present. For example, compounds of this invention defined in claim 2 can contain a –COOH group when R^2 = -$COOR^3$; R^6 = -$COOR^3$ or a group substituted with –$COOR^3$; or R^7 = -$COOR^3$ or a group substituted with –$COOR^3$; wherein R^3 = H. In claim 15, compound (20) contains a carboxyphenyl group, which can be esterified. In new claim 30, compound (12) contains a carboxyphenyl group, which can be esterified.

Pharmaceutically acceptable esters and their formation by reaction of a carboxylic acid group with an alcohol are standard knowledge to those skilled in the art. Additionally, examples of pharmaceutically acceptable esters are described in the specification at page 27, lines 29-30. Furthermore, examples of such esters are described in Example 18 (t-butyl ester) and Example 37 (ethyl ester) of the specification. As a result, the scope of the claimed subject matter, including pharmaceutically acceptable esters of the compounds of this invention, would be clear to one skilled in the art.

For the above-discussed reasons, independent claims 2 and 15 are believed to meet the requirements of 35 U.S.C. § 112, second paragraph. Since claims 3-14, 17-19 and 25 depend from and contain all the limitations of base claim 2, they likewise meet the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph against claims 2-15, 17-19 and 25.

New claim 30 is also believed to meet the requirements of 35 U.S.C. § 112, second paragraph, for the same reasons as discussed above for claims 2-15, 17-19 and 25.

Claim 21 stands rejected under 35 U.S.C. § 112, first paragraph. Claim 21 has been cancelled, without prejudice to the pursuit of the subject matter in another application, thereby rendering this rejection moot. This claim was cancelled in an effort to expedite prosecution and move more quickly toward an allowance of the pending claims. However, Applicants do not agree with the Examiner's position, and traverse this rejection for the record, since there is a reasonable expectation by those skilled in the art that compounds useful for the treatment of atherosclerosis will have a positive effect on atherosclerotic disease events; patients at risk for an atherosclerotic disease event can be identified by medical doctors using established guidelines and include those diagnosed with existing atherosclerosis (see, for example page 37, lines 1-14 of the instant specification); and dosage amounts for methods of use of the claimed compounds are described in the specification, for example at page 38, lines 3-9. Also, discussion of methods of treatment and prevention or reduction of risk for certain medical conditions including atherosclerotic disease events are described in the specification, for example at page 35, line 10 through page 37, line 14. Moreover, prevention of atherosclerotic disease events are not "unknown": the class of anti-atherosclerotic drugs most widely used in the clinic, statins, have been shown to decrease the burden of atherosclerosis in both mice (Sparrow et al. Arteriosclerosis Thrombosis & Vascular Biology, Volume 21, pages 115-121) and in humans (Nissen et al. Journal of the American Medical Association, volume 291, pages 1071-1080). Statins have also been shown to reduce the risk of major coronary events, coronary revascularization, and stroke (for a meta-analysis, see The Lancet, Volume 366, pages 1267-1278). LXR agonists have been shown to decrease the burden of atherosclerosis in

mice (Joseph et al. Proceedings of the National Academy of Sciences (USA) Volume 99, pages 7604-9). Therefore it is reasonable for one skilled in the art to believe that safe and efficacious LXR agonists would decrease both the burden of atherosclerosis and clinical events. Sufficient guidance for this utility is provided by the current application and state of the art as described above.

For the foregoing reasons, Applicants believe that the instant application is in condition for allowance, and an early notification thereof is earnestly solicited. If the Examiner has further questions or concerns regarding this application, he is invited to telephone the undersigned attorney at the number below.

Respectfully submitted,

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